The European Medical Device Market Re-Examined:
R&D Opportunities for MA companies in Germany
MassMEDIC Seminar at Massachusetts Medical Society

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Senior Manager Life Sciences
Germany Trade and Invest
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Agenda: R&D Opportunities for MA companies in Germany

Germany Trade and Invest

German Market Demand

German Medical Device Industry Landscape

Germany’s R&D in Medical Technology: Resources and Modus Operandi
A two-fold mandate: helping German exporters and attracting foreign investors

- *Germany Trade & Invest* is the foreign trade and inward investment promotion agency of the Federal Republic of Germany.

- The agency is promoted and fully funded by the Federal Ministry of Economics and Technology and the Federal Commissioner for the New Federal States. All services are free of charge.

- *Germany Trade & Invest*...
  - supports German export-oriented companies with comprehensive foreign market information.
  - promotes Germany as a high-performance economic and technology location to attract investors who create/secure jobs in Germany.
## Scope of Business

<table>
<thead>
<tr>
<th>For Companies in Germany (Exporters)</th>
<th>For Companies outside of Germany (Foreign Investors)</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Macroeconomic analyses and forecasts</td>
<td>▪ Pro-active approach of potential investors</td>
</tr>
<tr>
<td>▪ Country and industry analyses (over 125 countries)</td>
<td>▪ Identification of growth markets and competitor companies</td>
</tr>
<tr>
<td>▪ Foreign business and tax law</td>
<td>▪ Market entry strategy consulting</td>
</tr>
<tr>
<td>▪ Customs and tariffs information</td>
<td>▪ Industry specific information (e.g. Industry Teams)</td>
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<tr>
<td>▪ Practical business tips</td>
<td>▪ Site selection services</td>
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<tr>
<td>(e.g. business culture components)</td>
<td>▪ Tax and legal information</td>
</tr>
<tr>
<td>▪ Business contacts</td>
<td>▪ Project management support</td>
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</tbody>
</table>
Two Headquarters in Germany - 46 locations worldwide
Partner organizations of Germany Trade and Invest

- **Foreign Chamber Network**
  - 120 offices in 80 countries
  - Provides information about business opportunities in Germany

- **Embassies and Consulates**
  - 212 embassies and consulates in nearly all countries
  - Analysis of political and economic conditions
  - Consular services, e.g. visa questions

- **Industry Associations, Multipliers**
  - Supports and consults foreign investors with investment projects in Germany

- **Investment Promotion Agencies of the Federal States**
  - 46 offices on all continents
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Germany’s R&D in Medical Technology: Resources and Modus Operandi
German Market Demand: The Healthcare System

Healthcare spending in Germany accounts for 11.6% of GDP

- German Population – 82 million people (2011)
- About 70.3 million people in Germany have public health insurance
- 153 public health insurance companies with $ 164 billion expenditures in 2011
- 35% spent on hospital treatment
- 2064 hospitals with 502,749 beds in Germany (2010)
- Insurance system is currently generating surplus:
  - 2010: $ 6 billion
  - 2011: $ 4 billion

**Germany’s Insured Population – Health Insurance Breakdown (2011)**

- Public Health Insurance 87%
- Private Health Insurance 9%
- Other Health Insurance 4%
- Family insurance 27%
- Retired 24%
- Regular 49%

PHIC: Public Health Insurance Company

Source: DESTATIS: Gruddatem der Krankenhäuser 2011; BVMED – Branchenbericht 2011
The world market for medical devices in 2010 added up to EUR 224 billion.

**Market shares of the World MedTech Industry (in billion EUR)**

- US, 90
- Europe, 70
- Japan, 25
- Rest of Europe, 47
- Germany, 23
- Rest World, 40

- = 33% of European market
- = 10.5% of world market

**Total sales in the German Medical Technology industry (in billion EUR)**

- 2006: 16.24 (10.18 Foreign Sales, 6.06 Domestic Sales)
- 2007: 17.75 (11.34 Foreign Sales, 6.41 Domestic Sales)
- 2008: 19.13 (12.56 Foreign Sales, 6.57 Domestic Sales)
- 2009: 18.29 (11.43 Foreign Sales, 6.86 Domestic Sales)
- 2010: 19.85 (12.62 Foreign Sales, 7.23 Domestic Sales)

Source: BVMed Industry Report 2011
Germany’s most important medical device export markets include the European Union followed by North America and Asia.

**Development of external sales of medical devices (in € bn)**

- 2005: 9.4
- 2006: 10.4
- 2007: 11.1
- 2008: 11.5
- 2009: 11.3
- 2010: 12.8

**Destination countries of medical device exports (2009)**

- EU-27: 43%
- Asia: 16%
- North America: 20%
- Rest of Europe: 11%
- Others: 10%

Source: BVMed Annual Report 2011

Source: SPECTARIS Branchenbericht 2010, p.22
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German Market Demand

German Medical Device Industry Landscape

Germany’s R&D in Medical Technology: Resources and Modus Operandi
Germany is Europe’s innovation center for medical technology with 1244 patent applications in 2010.

Sources: Handelsblatt 2007, GTAI 2010 & European Patent Office Munich 2010

52 % of new ideas for medical devices are produced by clinical users
Jena: A Hot Spot for Medical Optics Technology

Cluster networks Optonet and Cooptics

- 170 member companies, 3 universities, 10 institutes
- 14,000 employees generate 2.7 billion EUR turnover
- **Examples for R&D collaboration:**
  - BioOptiSens Project: diagnostic options using the latest optical sensor developments
    Partners: *Analytik Jena AG, FSU of Jena, Jena Institute of Photonics, University Hospital of Jena*
  - HOKA Project: development of compact opto-electronic systems i.e. “the seeing pinpoint”
    Project partners: *Jenoptik AG, FSU of Jena, Fraunhofer Institute IOF*

R&D collaboration incentives

- **BMBF innovation competition** for medical technology grants approx. $1 million for each of the 16 annual winners.
- Examples:
  - **Beckman Coulter and Jena University**
    Women’s Hospital: project on prenatal diagnostics
  - **FSU of Jena**: project on minimally invasive implantation of mitral valves
  - **ZIM innovation program for SMEs**: grants approx. $500,000 to 2 collaborating partners

Real world impact: **15,000 projects funded with total of $2.6 billion**
Medical Valley EMN is one of Germany’s Leading Edge Clusters

Over 180 dedicated medical engineering companies

Projects worth about € 80 million will be completed by 2015

Main project topics include:

- Medical imaging
- Intelligent sensor technology
- Therapeutic systems
- Ophthalmology
- Horizontal innovations for product and process optimizations
German Medical Device Industry Landscape

Collaboration along the value chain and beyond industry borders.

**Machinery and Equipment Industry**
- Strongest in Europe
- 6,300 companies along the value chain

**Electronics and Microtechnology**
- More than 1 million jobs
- Highly innovative (€12 billion spent on R&D in 2011)

**Medical Technology**
Total Revenue: €23 billion

**Photonics and Consumer Optics Industry**
- Photonics: 1000 companies, 124,000 employees
- Consumer Optics: 150 companies, 21,400 employees

**Electromedical Industry**
- Home-use devices
- Digital medical imaging

Source: Germany Trade & Invest; SPECTARIS
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German Medical Device Industry Landscape

Germany’s R&D in Medical Technology: Resources and Modus Operandi
## Resources Overview

### Educated Workforce

<table>
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<tr>
<th>The Big Picture:</th>
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<tbody>
<tr>
<td>FTEs in R&amp;D</td>
<td>506,000</td>
</tr>
<tr>
<td>FTEs in R&amp;D that are scientists</td>
<td>299,000</td>
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<tr>
<td>Annually enrolling university students</td>
<td>500,000</td>
</tr>
<tr>
<td>Annual PhD graduates</td>
<td>25,000</td>
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### 2010 University Graduates in medical device related fields of expertise:

<table>
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<tr>
<th>Field</th>
<th>Number</th>
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<tbody>
<tr>
<td>Mathematics and Natural Sciences</td>
<td>63,497</td>
</tr>
<tr>
<td>Engineering</td>
<td>59,249</td>
</tr>
<tr>
<td>Medicine</td>
<td>23,752</td>
</tr>
<tr>
<td>Veterinary Medicine</td>
<td>1,399</td>
</tr>
</tbody>
</table>

### Support Network

- Some 750 publicly funded research institutions
- More than 400 universities
- About 130 technology networks and clusters in Medical Technology and related industries

### Funding

- Federal Government (BMBF, BMWi) funding options available
- Domestic expenditure on R&D is worth $80 billion

Sources: Destatis 2010; bmbf.de
Funding Example: KMU (SMEs) Innovative Scheme by the BMBF (Ministry of Research and Education)

- Eases access to research funding for companies supporting cutting-edge research in important future areas.

<table>
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<tr>
<td>Small and Medium Companies:</td>
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<tr>
<td>up to 50%</td>
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<tr>
<td>Research Organizations:</td>
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<td>up to 100%</td>
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<tr>
<td>Small Companies:</td>
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<tr>
<td>up to: 50 employees, EUR 10 million annual sales or EUR 10 million annual balance sheet total</td>
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<tr>
<td>Medium companies:</td>
</tr>
<tr>
<td>up to: 250 employees; EUR 50 million annual sales or EUR 43 million annual balance sheet total</td>
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</table>

Source: hightech-strategie.de
**Funding Example: Central Innovation Program SME (ZIM) by the BMWi (Ministry of Economics)**

- Supports companies in continuing to advance their research and innovation efforts, and develop new products, processes and services, in order to meet the challenges of global competition.

<table>
<thead>
<tr>
<th><strong>ZIM-KOOP:</strong> Funding Module Cooperation Projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Companies: up to 50%</td>
</tr>
<tr>
<td>Medium Companies: up to 45%</td>
</tr>
<tr>
<td>Research Organizations: up to 100%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>ZIM-SOLO:</strong> Funding Module Individual Projects</th>
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</thead>
<tbody>
<tr>
<td>Small Companies: up to 45%</td>
</tr>
<tr>
<td>Medium Companies: up to 35%</td>
</tr>
</tbody>
</table>

Source: bmwi.de
Education and research are the foundations for Germany’s future

- **417 Institutions of higher education**
  - 106 Universities
  - 207 Universities of applied science
  - 104 Others
- **5 Research Associations** (non-university affiliated)

### Leading German Research Associations

<table>
<thead>
<tr>
<th>Research Association</th>
<th>Profile</th>
<th>Annual Research Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DFG</strong> The German Research Foundation <a href="http://www.dfg.de">www.dfg.de</a></td>
<td>The DFG is the central, self-governing research funding organization that promotes research at universities and other publicly financed research institutions in Germany.</td>
<td>EUR 2 billion (2008)</td>
</tr>
<tr>
<td><strong>Helmholtz Association</strong> <a href="http://www.helmholtz.de">www.helmholtz.de</a></td>
<td>The Helmholtz Association is a community of 16 scientific-technical and biological-medical research centres employing 28,000 staff.</td>
<td>EUR 2.8 billion (approximately)</td>
</tr>
<tr>
<td><strong>Fraunhofer</strong> <a href="http://www.fraunhofer.de">www.fraunhofer.de</a></td>
<td>Germany’s Fraunhofer-Gesellschaft is Europe’s largest applied research institution. It employs a staff of 12,000 in 80 research units.</td>
<td>EUR 1.5 billion (of which around two thirds is generated from contract research)</td>
</tr>
<tr>
<td><strong>Leibniz Association</strong> <a href="http://www.wgl.de">www.wgl.de</a></td>
<td>The Leibniz Association is an interdisciplinary scientific community of 86 German research institutes. Twenty-five of these institutes are specialized in the field of life sciences.</td>
<td>EUR 1 billion (approximately)</td>
</tr>
<tr>
<td><strong>Max Planck Society</strong> <a href="http://www.mpg.de">www.mpg.de</a></td>
<td>More than 13,000 PhD students, postdoctorals, guest scientists and researchers, student assistants and other staff members work in the 80 research institutes of the Max Planck Society.</td>
<td>EUR 1.56 billion (2009)</td>
</tr>
</tbody>
</table>
Example: Fraunhofer Group

Europe’s largest organization for applied R&D

- Annual budget of $2.3 billion, $1.5 billion from contract research
- More than 80 research units in 60 institutes
- 20,000 FTE scientists and engineers
- Global presence: Research and representative offices in Europe, USA, Asia and Middle East
- Research topics:
  - Health/Nutrition/Environment
  - Safety/Security, IT
  - Transportation/Mobility
  - Energy/Living, Manufacturing Engineering
  - Medical Devices: Implants, Biodegradable Implants, Prostheses, Diagnostics, Assistance Systems/IT, Drug Development, Regenerative Medicine

Highlighted Services

- Technology development incl. prototyping
- Production method development and optimization
- Support of product introductions:
  - Conducting trials in demonstration centers
  - Training customer’s staff on site
- Technology assessment support:
  - Feasibility studies
  - Market surveys
  - Trend analysis reports
  - Environmental audits
  - Pre-investment analysis reports
- Supplementary services, e.g.
  - Funding support
  - Accredited testing services
Contact

Thank You

Germany Trade & Invest
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Modus Operandi

**Industry perspective:**
- Collaboration and contract research with nonprofit research institutions and universities
- IP transfer: in-licensing and purchase
- Integration in cluster activity
- Individual and ubiquitous funding programs
- Funding by National Hi-Tech Venture Funds

**Policy perspective (government):**
- Impetus on funding of industry and science collaboration, cluster activities, basic and applied (contract) research:
  - „Hi-Tech Strategy“
  - „Health Research Program“
  - Funding of non-profit scientific institutions

**Scientific institutions perspective:**
- Industry (fees for services) and public funding (direct funding, EU and national programs, collaboration between scientific institutes)
- IP transfer: (exclusive) out-licensing and sales

**Universities perspective:**
- Industry (facility and staff sponsoring, fees for services) and public funding (direct funding, EU and national programs, institute collaborations)
- IP transfer: (exclusive) out-licensing and sales

**Hospital perspective:**
- Partnering as opinion leaders (fees for services)
- Clinical Trials (fees for services)
- Contract Research: e.g. university hospitals (fees for services)
- IP transfer: (exclusive) out-licensing and sales via universities
- Partner for strategic reimbursement

**Modus operandi**

- **Industry**
- **Policy**
- **Universities**
- **Scientific Institutions (non-profit)**
- **Hospitals (and Practices)**
Industry Teams

Renewable Energy Team and core target segments

**Photovoltaics**
Germany is the largest PV-market in the world and disposes of one of the most innovative R&D networks.

**Energy Efficiency**
Germany is one of the leading markets worldwide in the field of energy efficiency.

**Wind Energy**
Germany by far has the world largest wind industry in the world. The offshore sector offers yet additional and large scale growth opportunities.

**Geothermal**
The German geothermal market is No. 3 in Europe.

**Bioenergy and Resources**
Germany is the leading consumer of bioenergy in Europe.

**Solar Thermal**
Germany is the largest market for solar thermal energy in Europe and the 2nd largest in the World.

**Energy Storage and Fuel Cells**
Germany is the No. 1 market for fuel cells in the EU.

**Closed Loop Recycling & Sustainable Water Technologies**
Germany is leading worldwide in these fields.

Foto-Quellen: Helmholtz Centre Berlin for Materials and Energy; © www.schwaebisch-hall.de Copyright Dreadlock/Fotolia; BMU/Rupert Oberhäuser, BSW/Paul Langrock; BMU/Brigitte Hiss; EWE AG / alpha ventus; Grüner Punkt GmbH, GFZ Potsdam; Schott Solar
Mechanical & Electronic Technology Team and core target segments

**Electronics**
With a market share of over 35 percent, German semiconductors dominate the European market.

**Automotive Industry**
Germany offers the biggest market potential and is home to an excellent highly-skilled labor force.

**Machinery & Equipment**
Germany is the world’s leading exporter and reaches a global market share of 19 percent.

**Aerospace Industry**
With an average growth of 9 percent the German aerospace industry is one of the most dynamic industry sectors.

**Maritime Technologies**
The German shipbuilding industry has a globally leading technological position and its suppliers are among the world’s export champions.

*Source: © Fraunhofer Verbund für Mikroelektronik*
Chemical Industry and Polymers
Germany is the biggest market for chemical products in Europe. Investors benefit from a unique chemical park concept with a range of services and professional management.

Chemicals-Related Process Industry (e.g. paper and glass/ceramic industry)
The paper industry is number one in terms of production in Europe. After the USA, China, Japan and Canada it ranks fifth in the world.

New Materials/ Composite Materials
Composite materials and composite material systems have gained in importance. There is an increasing demand for light, low-abrasive and temperature-resistant polymers, metals and ceramics.

Red Biotech
With nearly 400 “dedicated” biotechnology firms Germany is home to more biotech companies than any other country in Europe. Between 2000 – 2004, 30% of all worldwide bio patent applications at the Patent office in Munich came from Germany.

Medical Devices Industry
Germany is the third largest market for medical devices worldwide and leading in Europe. The competitive advantage: decade long experience in the art of engineering, creativity and enthusiasm for innovation.

Pharmaceuticals Industry
Germany is Europe’s largest single market for pharmaceuticals. The market is attractive due to Germany’s stable and broad health system. Furthermore, Germany is open to both innovation and low-priced providers.

Source: 1Gustavo Alabiso/ Visum, Papierfabrik Palm, www.igcbe.de, 2www.bam.de, 3VfA © Lilly Pharma; 4BVmed © B.Braun Melsungen AG; 5VfA © Takeda Pharma
Industry Teams

Service Industry Team and core target segments

**Information & Communications Technology (ICT)**
Germany’s ICT and E-Commerce industries are market leaders in Europe with sales of EUR 146 billion (ICT) and EUR 438.7 billion (E-Commerce) respectively.

**Business Services**
Annual employee growth in Germany’s contact center at over 15 percent; over 6,000 service centers with more than 450,000 agents.

**Transportation & Logistics**
Annual growth rate of around 8.5 percent with a total turnover of EUR 204 billion in 2007; easy access to all European markets thanks to favorable central location in Europe.

**Consumer Goods/Retail**
Europe’s largest consumer market with more than 82 million consumers and private spending on consumer goods totaling total EUR 363.6 billion.

**Food & Beverages**
With an annual turnover of EUR 147 billion, Germany is Europe’s largest food and beverage producer. Current growth segments include convenience, organic, and functional food products.

**Tourism & Leisure**
129.9 million tourists traveled to Germany in 2007, with 361.8 million registered overnight stays. The number of overnight stays is increasing steadily.